Clinical Use of a New Mitral Disc Valve

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■ *A disc valve of new design was used successfully for the replacement of the mitral valve in patients with rheumatic mitral valve disease. This valve would appear to have the following advantages over the mitral ball valve prosthesis:*

- *Lower left atrial pressure after replacement.*
- *Elimination of the hazard of left ventricular outflow tract obstruction with mitral valve replacement.*
- *Decreased incidence of thromboembolization.*
- *Abolition of possibility of ventricular septal irritation.*

Despite the better outlook for this valve compared with the ball valve for mitral valve substitution, the mitral valve should always be repaired whenever feasible. Repair is possible in the majority of patients.

USUALLY THE BEST treatment for a stenotic or insufficient mitral valve is surgical repair, but there are some patients in whom prosthetic valvular replacement is necessary—patients with moderate to pronounced calcification of the valve or decided fibrotic deformity. In patients with mitral insufficiency we have found repair to be of permanent value and free of the serious complication of peripheral embolization which may occur following replacement with a ball valve.

Because of the high incidence of peripheral embolization, the possible occurrence of left ventricular outflow tract obstruction, and the arrhythmia due to ventricular septal irritation that may occur with mitral ball valve replacement, we developed a disc valve (Figure 1). Experimentally in dogs this valve appeared to have important advantages over the ball valve. Following good experimental results, the valve was used clinically for mitral valve substitution in 14 patients with rheumatic mitral valve disease in whom repair of the valve was not possible. Between the time of the first and the fourteenth replacement operation using the disc valve a total of 73 patients were operated upon for mitral valve disease, 59 of them having had repair of the existing valve. In the following case, prosthetic replacement was carried out.

Report of a Case

The patient, a woman born in 1933, had rheumatic fever at the age of nine years and had had shortness of breath since the age of 13. When she consulted us in October 1962, she had pronounced symptoms of congestive failure, including paroxysmal nocturnal dyspnea, chronic cough and inability

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Aided by grants HE 09223-02 and HE 09883-01 from the United States Public Health Service, grants 354 and 373 from the Los Angeles County Heart Association, a grant from the Children's Heart Foundation of Southern California, and a grant from the Los Angeles Thoracic and Cardiovascular Foundation.

Submitted 9 September 1966.

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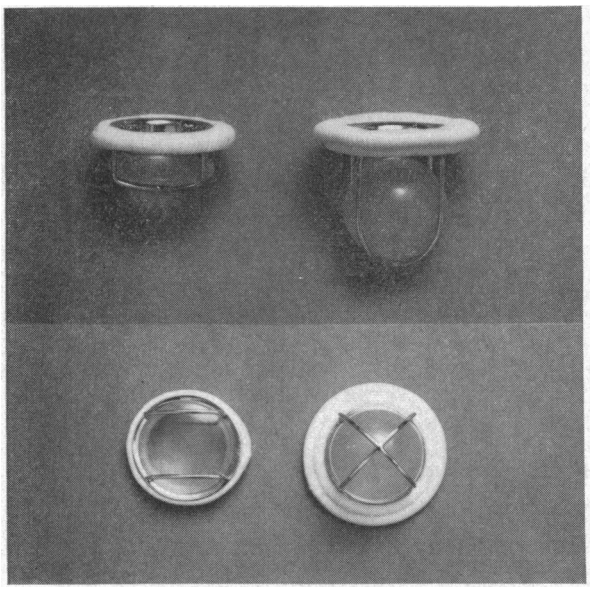

Figure 1.—On the right is the Starr-Edwards ball valve and on the left the new Kay-Shiley disc valve. Note that for the same cross sectional area, there is a pronounced decrease in the length of the cage, as well as the size of the disc compared with the ball. Note also the parallel rather than perpendicular struts.

to be out of bed because of dyspnea and fatigue. She was on a low salt diet and was taking digitalis and diuretics. A benign tumor of the breast had been removed in 1958 and a hysterectomy and partial removal of the bladder was performed in 1960 for a carcinoma.

On physical examination, blood pressure was 95/60 mm of mercury. The pulse had a sinus rhythm. The cardiac apex was at the left sixth intercostal space at the anterior axillary line. There was a grade V/VI apical diastolic rumble, an opening snap and a loud M_1. There was a grade IV/VI systolic murmur immediately to the left of the sternum at the fourth intercostal space. No rales were noted and there was no leg edema or hepatomegaly.

An electrocardiogram was consistent with right and left atrial hypertrophy as well as right ventricular hypertrophy. There was sinus rhythm with occasional ventricular premature contractions.

X-ray studies showed grade IV/VI cardiac enlargement. This included grade III/VI enlargement of the right and left atria and grade II/VI enlargement of the right and left ventricles. The changes described were indicative of combined mitral stenosis and insufficiency as well as tricuspid insufficiency.

Operation was carried out 30 November 1962, with extracorporeal circulation through a heart-lung machine. The mitral valve was found to be heavily calcified and stenotic and there was pronounced calcification of the aortic leaflet. The mural leaflet was rigid and thickened. There was insufficiency at the center of the valve. The valve orifice admitted one finger. A knife and finger fracture technique was used to open the anterolateral commissure. The chordae tendinae were shortened and fused. The posteromedial commissure was also opened through a great deal of calcium. Posteromedial annuloplasty was performed.[8] This valve was obviously a very poor one, but because this was early in the history of valve replacement, it was deemed wise to repair rather than replace the valve. At the end of the repair procedure, the valve was rigid but admitted two fingers and was no longer insufficient. Examination of the tricuspid valve revealed stenosis rather than insufficiency. The valve admitted one to one and one-half fingers and there was fusion of all three commissures. The commissure between the anterior and the septal leaflet was opened with a knife and the tricuspid valve then easily admitted two fingers without evidence of tricuspid insufficiency.[13]

A tracheostomy was performed. The patient's postoperative course was prolonged and she left the hospital on the 29th postoperative day. She did well at home and continued to improve. After a time she was able to carry on with her household duties and look after her small children, but in February 1965 she began to notice dyspnea on exertion and she had difficulty with housework. She had no orthopnea nor paroxysmal nocturnal dyspnea. At that time she was taking digitalis and was following a low salt diet.

When the patient was examined on 9 September 1965, the blood pressure in the right arm (recumbent) was 120/70 mm of mercury with a sinus rhythm. She had a chronic cough and rales were noted at the right base posteriorly. There was one plus edema. The liver was not tender but the edge was palpable two to three fingerbreadths below the costal margin.

The apex of the heart was at the fifth intercostal space midway between the midclavicular line and the anterior axillary line. There was a moderate right ventricular lift. A grade III/VI apical diastolic rumble was present and there was a grade II/VI apical systolic murmur, as well as a grade IV/VI systolic murmur just to the left of the sternum at the fourth intercostal space.

The answering of questions and undressing and dressing caused pronounced dyspnea.

Right and left heart catheterization were performed 19 October and the pulmonary artery pressure was 42/22 mm of mercury, rising to 70/42 with exercise. Pulmonary wedge pressure was 25/15 mm. Right atrial pressure was 9/-3. The cardiac index was 2.3 liters per minute at rest and 3.8 liters with exercise.

Operation was carried out 18 November. Through a median sternotomy incision, grade III/VI enlargement of the right atrium was noted and there was III/VI systolic thrill in the right atrium. The left atrium was enlarged. There was a grade III/VI diastolic thrill in the left ventricle. A catheter was inserted into the right internal mammary artery to measure pressures, and another was inserted into the ascending aorta to return oxygenated blood to the patient.[7] On palpation of the tricuspid valve before circulatory by-pass was begun, there was found to be no evidence of tricuspid stenosis, but instead there was secondary tricuspid insufficiency, grade III/VI, with a valve and annulus that admitted three to three and a half fingers.

After by-pass was in effect, examination revealed calcification of the mitral valve. There was pronounced calcification of the anterior leaflet as well as the area of the posteromedial commissure. The mural leaflet was again found to be fibrotic, thickened and rigid. The valve was removed and a No. 6 Kay-Shiley disc valve* (identical diameter and cross sectional area to the Starr-Edwards No. 3 ball valve) was sutured in place with interrupted mattress sutures in such a fashion that the 3 millimeters of the remaining mitral valve covered the prosthetic device. Therefore, the disc valve was subvalvular and in the ventricle.[11]

On examination of the tricuspid valve under direct vision, no evidence of stenosis was seen but there was secondary tricuspid insufficiency. Two figure-of-eight sutures were placed in the annulus of the tricuspid valve in such a way that the posterior leaflet was almost completely obliterated. These sutures were placed in the annulus from the area of the commissure between the septal and posterior leaflet toward the commissure between the anterior and posterior leaflet. When the sutures were tied, the tricuspid annulus was narrowed to two fingerbreadths.[8]

*Manufactured by Shiley Laboratories, 13431 Eton Place, Santa Ana, Calif.

The patient did well postoperatively and a tracheostomy was not necessary. Catheterization was performed in April 1966 (five months after operation), and the pulmonary artery pressure was 35/15 mm of mercury, rising to 50/20 with exercise. Pulmonary wedge pressure was 16/5 mm and the right atrial pressure was 5/0 mm. The cardiac index was 2.5 liters per minute at rest and 3.3 liters with exercise.

Discussion

The importance of repairing the valve rather than replacing it with a prosthetic device has been stressed in the past.[3,6,9,10] During the past eight years we have become convinced of the necessity of reconstructing valves whenever possible rather than replacing them. Starr noted an incidence of 27 emboli in 65 patients who were observed a minimum of three months after ball valve replacement of the mitral valve.[4]

Peripheral embolization is not a complication of mitral valve repair and the majority of patients with mitral insufficiency can have repair of the insufficient mitral valve with annuloplasty. The valve most amenable to correction is the one with gross dilatation and pliable leaflets, with or without torn chordae tendineae. However, even a valve with combined mitral stenosis and insufficiency can be repaired in some patients, provided there is not too much deformity or calcification. The only valves that cannot be repaired are those with moderate to heavy calcification or with severe scarring and fibrosis.

Clinically, there have been two serious problems with mitral ball valve replacement. One is the high incidence of peripheral embolization and the other is outflow obstruction from the left ventricle. Byron[1] mentioned irritation of the ventricular septum, with arrhythmia and death, as another complication.

Cross, Ferein and Jones[2] and Hufnagel and Conrad[5] have reported on other types of disc valves.

Because of our problems with the ball valve, we also developed a disc valve. It has been used experimentally in our research laboratory for the past two years and during that time it was compared with the conventional ball valve in the mitral and tricuspid area of dogs.[11] The following observations were noted in comparing these two valves. There was a lowering of the incidence of thrombosis with the disc valve compared with the ball valve. The left atrial pressure was significantly

lower in the dogs with the disc valve in the mitral position. Recent studies by Morrow, Harrison and Braunwald[12] indicated that although hemodynamic abnormalities regress after use of the ball valve, a diastolic gradient that increases during exercise persists across the valve. In our experiments, it was noted that with mitral ball valve replacement there was a gradient at the outflow area of the left ventricle. This gradient was 25 mm of mercury or more in five of eight dogs. This either did not occur with the mitral disc valve or else was minimal compared with that of the ball valve.

In our patients with ball valve replacement, we most commonly used a No. 2 or No. 3 Starr-Edwards ball valve, approximately half of the patients having the smaller size and half the larger. It was rare for a patient to have insertion of the largest (No. 4) ball valve or the smallest (No. 1). For the 14 patients with disc valve replacement (Table 1) either a No. 6 or a No. 7 was used, these sizes having the same inside diameter and cross sectional area as the No. 3 and No. 4 ball valves. Therefore, these patients had a larger valve inserted than was possible with the ball valve. Larger sized disc valves have been manufactured and will be inserted in patients with large left ventricles. The size of the valve inserted is probably important in decreasing the left atrial pressure and also in decreasing left atrial stagnation. Since the disc valve cage is only 40 per cent as long as the ball valve, the disc valve can be inserted beneath the remaining 3-millimeter cuff of the patient's valve tissue.[12] This allows for a shield of valve tissue over the disc valve, except for the 1-millimeter ring of Stellite.®* This technique cannot be used routinely for

*A cobalt base metal similar to vitalium, made by Union Carbide Corp.

TABLE 1.—*Data on 14 Cases in which Cardiac Valves were Replaced with Disc Valves*

	Diagnosis	*Procedure*	*Result*
1.	(a) Calcified valve with mitral insufficiency (b) Tricuspid insufficiency	(a) Replacement of mitral valve with a No. 6 disc valve (b) Tricuspid valvuloplasty	Asymptomatic
2.	Mitral stenosis and insufficiency	Mitral valve replaced with a No. 7 disc valve	Asymptomatic
3.	Mitral stenosis and insufficiency	Mitral valve replaced with a No. 6 disc valve	Asymptomatic
4.	Mitral stenosis and insufficiency	Mitral valve replaced with a No. 7 disc valve	Asymptomatic
5.	Mitral stenosis and insufficiency	Mitral valve replaced with a No. 6 disc valve	Embolus three months after surgery resulted in aphasia and hemiplegia (prothrombin time 50 per cent at that time)
6.	(a) Calcific mitral stenosis and insufficiency (b) Tricuspid insufficiency	(a) Mitral valve replaced with a No. 6 disc valve (b) Tricuspid annuloplasty	Asymptomatic (See paper for summary)
7.	Mitral stenosis and insufficiency	Mitral valve replaced with a No. 7 disc valve	Asymptomatic
8.	Calcific mitral stenosis	Mitral valve replaced with a No. 5 disc valve	Asymptomatic
9.	(a) Calcific mitral stenosis (b) Aortic stenosis and insufficiency	(a) Mitral valve replaced with a No. 6 disc valve (b) Aortic valvuloplasty	Asymptomatic
10.	Mitral stenosis	Mitral valve replaced with a No. 6 disc valve	Died in low cardiac output
11.	Mitral insufficiency	Mitral valve replaced with a No. 9 disc valve	Asymptomatic
12.	(a) Mitral stenosis and insufficiency (b) Tricuspid insufficiency	(a) Mitral valve replaced with a No. 6 disc valve (b) Tricuspid annuloplasty	Died of aspergillus endocarditis
13.	(a) Mitral stenosis (b) Tricuspid stenosis and insufficiency (c) Aortic stenosis	(a) Mitral valve replaced with a No. 6 disc valve (b) Tricuspid valve replaced with a No. 8 disc valve (c) Aortic valvuloplasty	Asymptomatic
14.	Mitral insufficiency	Mitral valve replaced with a No. 7 disc valve	Asymptomatic

ball valve substitution, since it lowers the valve into the left ventricle and therefore (with the ball valve) increases the risk of left ventricular outflow tract obstruction and causes irritation of the ventricular septum. The disc valve has been laboratory-tested for the equivalent of 35 years without any evidence of wear. However, with the ball or disc valve machined correctly, this is not an important factor as compared with moving leaflet valves, which wear out rather rapidly. The disc valve that we used has been machined in such a fashion that disc sticking is impossible.

Four of the 14 patients in whom the mitral valve was replaced with a disc valve had tricuspid valve involvement as well. In three patients the tricuspid valve was repaired but in the fourth it was necessary to replace the valve with a disc valve. In two patients there was concomitant aortic valve disease and in both of these patients the valve was repaired. There were two deaths in this group of 14 patients. In one patient, death was due to aspergillus endocarditis; in the other, to low cardiac output.

There was one peripheral embolus in these 14 patients. It occurred three months after insertion of the mitral disc valve, and the patient's prothrombin time was 50 per cent at the time of embolization rather than the desired 20 per cent.

Anticoagulant therapy should be employed in all patients with prosthetic valves.

ADDENDUM: At present 18 more patients have had mitral valve replacement with the Kay-Shiley disc valve and the results have been comparable.

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